41. The intubation instrument of claim 25, wherein said viewer is a Complementary Metal Oxide Semiconductor camera.

42. The intubation instrument of claim 25, wherein said lifter portion is pivotally secured to said base portion.

43. The intubation instrument of claim 42, further including a Light Emitting Diode operably secured to said lifter portion.

44. The intubation instrument of claim 41, further including a display operably secured to said camera.

REMARKS

A first Office Action, dated November 30, 2001, rejects claims 1-30. reconsideration is respectfully requested in light of the amendments and the following remarks.

Formalities

Applicant has corrected the above-noted objections in the drawings and specification. However, applicant has not removed element numbers 212, 207, 110, and 46 from the drawings. These element numbers are fully supported by the specification. In particular, element 212 is for Light Emitting Diodes (Page 16, line 15). Element 207 is for a defined length (Page 15, line 21) of the base portion. Element 110 is an alternative channel (Page 20, line 2), and element 46 is the anterior surface (Page 8, line 9).

Applicant has also clarified the terminology of the pharynx area of the human respiratory system. In particular, applicant has replaced the archaic term "hypopharynx" with the more current term "pharynx". Moreover, this area is becoming more commonly referred by those skilled in the art as the nasopharynx 32a (FIG. 6), the oropharynx 32b (FIG. 6), and the laryngopharynx 32c (FIG. 6). Accordingly, these regions of the human respiratory system have been specifically identified.

The specification and claims have been amended to clarify the acronyms CMOS, CCD, and LED, and a terminal disclaimer has been included with this amendment to overcome the Examiner's non-statutory double patenting rejection.

Claims 9-15, 23, 24, 26 and 28-30

The Examiner's only rejections of claims 9-15, 23, 24, 26 and 28-30 are limited to relatively minor formalities, which have been corrected herein. Accordingly, applicant has interpreted the Examiner's office action as indicating these claims would be allowable if amended to place them into independent format with all the limitation of their associated base claims incorporated therein. Therefore, applicant has so amended these claims, and they should now be in condition for allowance.

Rejections Under 35 USC § 103

Claims 1-8, 16-22, 25, 27 stand rejected under 35 USC § 103 as being obvious over U.S. Pat. No. 5,203,320 to Augustine ("Augustine") in view of U.S. Pat. No. 5,016,614 to MacAllister ("MacAllister"). Applicant has clarified the scope of protection sought by the claims and also respectfully traverses these grounds for rejection.

Claim 1

Claim 1 has been amended to specifically claim the structures of the intubation instrument in relationship to particular elements of the human respiratory system. For example, in claim 1, the elongate base portion is "long enough to extend through the patent's mouth into the patient's oropharynx," and the elongate lifter portion extends at an angle from the base portion and is long enough to "extend into the laryngopharynx and operably engage the epiglottis of the patent when the elongate base portion is extended into the patient's oropharynx."

None of the references teach or suggest such a structure. Augustine teaches using an elongate member that is curved to conform around the back portion of the patient's tongue. MacAllister teaches inserting a straight elongate member into the patient's mouth.

Since none of the references of record teach or suggest the limitations of amended claim 1, they cannot anticipate or render obvious this claim. Accordingly, it should now be in condition for allowance. Moreover, since dependant claims 2-8, and 16-18, and new claims 31-37 depend on now allowable claim 1, they too should now be in condition for allowance.

Claim 19 and 25

Similarly, claims 19 and 25 have been amended to clarify that the lifter portion is about as long as the base portion. This orientation provides optimal viewing when the viewer is placed at the transition between the two portions, and it provides an optimal shape to allow easy, consistent, and accurate insertion of the instrument into a patient.

Considerable skill is required to accurately insert a traditional intubation instrument into a patient. In contrast, testing has revealed that the intubation instrument of the present invention can be easily and accurately inserted, even by relatively inexperienced medical personnel. Applicant believes that the lengths and orientation of these components is the primary reason the intubation instrument of the present invention is so easy to use. Should the examiner remain unconvinced, applicant would be happy to provide the examiner with objective evidence from disinterested third parties that attests to the benefits of a commercial embodiment of the present invention caused by the unique orientation and lengths of the base and lifter portions.

None of the references of record teach or suggest a structure where the lifter portion is about as long as the base portion. Accordingly, claims 19 and 25, as amended, should now be in condition for allowance. Moreover, since dependent claims 21-22, 38, and 40-44 depend on now allowable claims 19 or 25, they too should be in condition for allowance.

Claims 6-8

Applicant respectfully traverses the Examiner's rejections that suggest the degrees of the angle between the base and lifter portions is somehow a matter of design choice. As previously noted, the design of the present invention is much easier for a medical professional to use. Applicant believes that the angle between the lifter portion and base portion is a contributing reason to why the present invention works so well.

However, none of the references teach or suggest structures that either interact with particular structures of the human respiratory system (Claim 1), or have a lifter portion about the same length as the base portion (Claims 19 and 25). In contrast, the known intubation instrument inventions teach of structures that are oriented differently within a patient's respiratory system. Accordingly, no amount of experimentation with

the components of these known intubation instruments could lead one skilled in the art to find the optimal angle between the base and lifter portion of the present invention as claimed.

In view of the foregoing, applicant submits that all of the currently pending claims 1-44 are in condition for allowance and respectfully requests that the case be passed to issuance. If the Examiner has any questions, she is invited to contact applicant's attorney at the below-listed telephone number.

Respectfully submitted,

April 30, 2002

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ATTACHMENT A
Redlined changes to substitute paragraphs

Please replace the paragraph beginning on page 4, line 8 with the following paragraph:

In accordance with one aspect of this invention, the instrument provides a blade or arm having an elongate base portion and an elongate lifter portion having a distal end thereof extending therefrom, preferably at an angle between 15° to 85°, inclusive. The lifter is sized and shaped to engage, lift and support the patient's epiglottis, thereby to expose the glottis. In a preferred embodiment, the base portion and lifter portion are substantially the same length, and a viewing device, which is preferably a Charged Coupled Device ("CCD") or Complementary Metal Oxide Semiconductor ("CMOS") camera positioned near the transition portion between the base and lifter portions, is aligned to provide a perspective view toward the distal end of the lifter. Lights, which are preferably Light Emitting Diode ("LED") units, are positioned toward the distal end of the lifter to facilitate viewing. A transparent protective sheathing may be positioned over the assembly to facilitate cleaning and provide sterile multiple use of the device.

Please replace the next two paragraphs beginning on page 7, line 20 with the following paragraphs:

As noted, the instrument is inserted, distal end 26 first, through the patient's mouth 30. As explained below, when properly inserted, the distal end of the endotracheal tube 40 resides in the [hypo]pharynx 32. Recently, individual portions of the pharynx 32 have become more commonly referred by those skilled in the art as the nasopharynx 32a (FIG. 6), the oropharynx 32b (FIG. 6), and the laryngopharynx 32c (FIG. 6). Accordingly, using these commonly known and more precise terms of the human respiratory system, the endotracheal tube 40 resides in the laryngopharynx 32c (FIG. 6). The patient's epiglottis 34 is supported by the instrument in a manner to expose the glottis 36. In the present invention, the instrument provides for the telescopically observed advance of the leading end 38 of an endotracheal tube 40 through the glottis 36, into the larynx 42 adjacent to the vocal cords 44. As is known in the art, an endotracheal tube 40 permits air to be conducted to and from an incapacitated patient. The present instrument includes a number of features that greatly increase the ease with which the instrument [20] and tube 40 can be properly located and continuously observed via a telescope or

other optic device.

More particularly, the arm 22 of the instrument [20]is configured to define in the handle 24 and on its anterior surface 46 a guide path for the smooth advance of the tube 40 relative to the inserted instrument[20]. For the purpose of this description, the anterior surface 46 of the instrument is, as shown [if]in Fig. 6, that facing the lower jaw 48 of the intubated patient.

Please replace the paragraph beginning on page 9, line 6 with the following paragraph:

The side edges 54 terminate in a loop 60 that is part of the instrument and protrudes from the distal end 26 of the instrument at an angle 55 (FIG. 1) of about 45 degrees relative to the length of the arm 22. As viewed from the end (Figs. 2 and 5), the loop defines an elongated opening 64 through which extends the leading end 38 of the tube 40.

Please replace the paragraph beginning on page 10, line 16 with the following paragraph:

Once the arm 22 is in place, the guard 70 serves to prevent the tissue in the [hypo]pharynx 32 from contacting the distal end 26 of the arm 22 and obstructing the view available to a viewer that is carried by the instrument. In this embodiment a telescope 80 is shown. In this regard, the telescope 80 is one that terminates in a long tubular member having an objective lens at its end 82. The terminus of the telescope fits into a telescope passage 83 that is formed through the arm 22. The telescope also includes a light post 86 that is mounted to the telescope 80 near the outer end 88 of the passage 83 and that provides illumination to the telescope 80. In a preferred embodiment of the instrument, a suitable telescope is one having approximately a 25-degree viewing angle; such as manufactured by Henke-Sass, Wolf of America Inc., Southbridge, Massachusetts, as model number 8853.42.

Please replace the next two paragraphs beginning on page 15, line 16 with the following paragraphs:

Preferably, the lifter portion 204 is at least approximately 3 centimeters long, and the angle 208 between the base portion 202 and lifter portion 204 is between 5° and 90°, inclusive.

More preferably, the length 205 of the lifter portion 204 is between approximately 4 centimeters and 8 centimeters long, and the angle 208 between the lifter portion 204 and base portion 202 is between 30° and 60°. Even more preferably, the length 205 of the lifter portion 204 is approximately the same as the length 207 of the base portion 202, both of which are approximately 6 centimeters long, and the angle 208 between the lifter and base portions is approximately 45°. Obviously, the overall geometry between the base portion [2020]202 and lifter portion 204 is important for effective operation of the instrument. Proportionately smaller sizes should be used for pediatric applications.

A viewing device, which is preferably a camera 80' operably secured to the instrument, is preferably positioned along the posterior surface of the lifter portion 204, near the transition portion between the base and lifter portions 202, 204, respectively, and aligned to provide a perspective view toward the distal end 210 of the lifter portion 204. More preferably, the camera 80' is mounted to the left side of the instrument when viewed from the handle 25, thereby permitting passage directly down the midline of the patient's tongue. The lifter portion [202]204 protects the camera from being blocked by tissue and debris. Moreover, positioning the camera 80' away from the distal end 210 of the lifter portion 204 provides the user with a clear perspective view of the entire area.

Please replace the paragraph beginning on page 16, line 22 with the following paragraph:

The camera 80' is preferably a Complementary Metal Oxide Semiconductor ("CMOS") or Charged Coupled Device ("CCD") hybrid camera, both of which are more compact, light weight, light sensitive, and economical, than traditional cameras used in such applications. Known manufacturers and sellers of such cameras include Sun Microsystems, Amain Electronics, and Misumi Electronics. Preferably, the camera 80' is operably connected to a power source 214, such as a battery or A/C connection, and suitable related electronics 216 , which are stored in the handle 24 of the instrument. As best shown in Figs. 11A&B, the camera 80' is operably connected to a display 218, either by a direct (Fig. 11B) or remote (Fig. 11A) connection. Such remote connections can include a transmitter 220 received within the instrument and the display 218 including a receiver 222 for receiving video signals from the transmitter 220. Alternatively, such a system can include infrared technology or the like. The camera 80' and related transmitter 220 can also communicate with a display, or other

equipment such as remote locations via the evolving industry standard more commonly known as "bluetooth." Such communication can also be used to transmit the information via the Internet or the like, thereby facilitating real-time remote incident analysis, advice, assistance, and/or teaching.

Please replace the paragraph beginning on page 19, line 6 with the following paragraph:

In particular, a locking mechanism 307, such as an actuation lever 300 having a handle 302 at one end extends through a channel 304 in the base portion 202 to pivot the lifter portion 204 about pivot point 301. Detents 306 between the actuation lever and base portion allow a user to select the desired angle 208 between the lifter portion [208]204 and base portion 202, and lock that position in place. Accordingly, by manipulating the actuation lever, the optimal angle 208 between the lifter portion 204 and base portion 202 for a particular patient may be selected on site by the practitioner.

ATTACHMENT B
Redlined changes to claim

1. (Amended) An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

a body having a handle attached thereto;

an elongate arm [having an elongate base portion attached to the body,]having an elongate base portion operably secured to said body at one end and an elongate lifter portion extending from said elongate base portion toward an opposite end of said elongate base portion thereby defining an angle between said elongate base portion and said elongate lifter portion,

said elongate base portion having a first defined length, said first defined length being long enough to extend through the patient's mouth into the patient's oropharynx;

said elongate lifter portion having,

a distal end for insertion distal-end first through a patient's mouth,

a second defined length, said second defined length being long enough to extend into the laryngopharynx and operably engage the epiglottis of the patent when the elongate base portion is extended into the patient's oropharynx, and, [having]

a smooth surface for engaging the patient's epiglottis, [and a distal end for insertion distal-end first through a patient's mouth;

said lifter portion being at least 3 centimeters long and extending from said base portion by at least a 5 degree angle.]

2. (Amended) The intubation instrument of claim 1, further including a viewer positioned in the vicinity of the area where the base portion meets the lifter portion of the elongate arm, said viewer directed toward the distal end of the lifter portion.

4. (Amended) The intubation instrument of claim 2, wherein said viewer is a Complementary Metal Oxide Semiconductor [CMOS] camera.

5. (Amended) The intubation instrument of claim 2, wherein said viewer is a Charged Coupled Device [CCD] camera.

6. (Amended) The intubation instrument of claim 1, wherein said [at least 5°]

angle is between 5° and 85°, inclusive.

7. (Amended) The intubation instrument of claim 6, wherein said [at least 5°] angle, is between 30° and 60°, inclusive.

8. (Amended) The intubation instrument of claim 6, wherein said [at least 5°] angle is approximately 45°.

9. (Amended) [The intubation instrument of claim 2, further including] An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

a body having a handle attached thereto;

an elongate arm having an elongate base portion attached to the body and an elongate lifter portion having a smooth surface for engaging the patient's epiglottis, said elongate lifter portion having a distal end for insertion distal-end first through a patient's mouth;

said lifter portion being at least 3 centimeters long and extending from said base portion by at least a 5 degree angle;

a viewer positioned in the vicinity of the area where the base portion meets the lifter portion of the arm, said viewer directed toward the distal end of the lifter portion; and,

a light operably secured to said lifter portion.

10. (Amended) The intubation instrument of claim 9, wherein said light is a Light Emitting Diode[an LED].

11. (Amended) The intubation instrument of claim 9[2], wherein said viewer is Complementary Metal Oxide Semiconductor[an CMOS] camera and [further including] said light is a Light Emitting Diode[an LED light] operably secured to said lifter portion.

12. (Amended) [The intubation instrument of claim 1,] An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

a body having a handle attached thereto;

an elongate arm having an elongate base portion attached to the body and an elongate lifter portion having a smooth surface for engaging the patient's epiglottis, said elongate lifter portion having a distal end for insertion distal-end first through a patient's mouth and [wherein said lifter portion is]pivotally secured to said base portion at a pivot point[.];

said lifter portion being at least 3 centimeters long and extending from said base portion by at least a 5 degree angle.

13. (Amended) The intubation instrument of claim 12, further including a locking mechanism[lever arm] for actuating and holding said lifter portion in a [preselected]predetermined position about said pivot point.

14. (Amended) The intubation instrument of claim 12[2], further including a display for viewing video output from said viewer.

19. (Amended) An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

a body having a handle attached thereto;

an elongate arm having an elongate base portion [attached to the body] operably secured to said body at one end and an elongate lifter portion extending from said elongate base portion toward an opposite end of said elongate base portion, said elongate lifter portion having a smooth surface for engaging the patient's epiglottis and a distal end for insertion distal-end first through a patient's mouth;

said lifter portion being at least as long as said base portion and extending from said base portion by at least a 5 degree angle.

21. (Amended) The intubation instrument of claim 20[21], wherein said viewer is a Complementary Metal Oxide Semiconductor [CMOS] camera.

22. (Amended) The intubation instrument of claim 21, wherein said viewer is a Charged Coupled Device[CCD] camera.

23. [The intubation instrument of claim 21, further including] An intubation

instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

a body having a handle attached thereto;

an elongate arm having an elongate base portion attached to the body and an elongate lifter portion having a smooth surface for engaging the patient's epiglottis, said lifter portion having a distal-end for insertion distal-end first through a patient's mouth and being approximately as long as said base portion and extending from said base portion by at least a 5 degree angle;

a complementary metal oxide semiconductor camera positioned in the vicinity of the area where the base portion meets the lifter portion of the arm, said camera directed toward the distal-end of the lifter portion; and,

a light operably secured to said lifter portion.

24. (Amended) The intubation instrument of claim 23, wherein said light is a Light Emitting Diode[an LED].

25. (Amended) An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

a body having a handle attached thereto;

an elongate arm having an elongate base portion attached to the body and an elongate lifter portion extending from said elongate base portion, said elongate base portion having a first defined length, said elongate lifter portion having a second defined length and[having] a smooth surface for engaging the patient's epiglottis and a distal end for insertion distal-end first through a patient's mouth,

said second defined length being about as long as said first defined length; and,

a viewer secured posterior to said arm in the vicinity where said base portion meets said lifter portion, said viewer directed toward the distal end of the lifter portion.

26. (Amended) [The intubation instrument of claim 25, wherein] An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

a body having a handle attached thereto;

an elongate arm having an elongate base portion attached to the body and an elongate lifter portion having a smooth surface for engaging the patient's epiglottis, said lifter portion having a distal end portion for insertion distal end portion first through a patient's mouth.

a viewer secured posterior to said arm in the vicinity where said base portion meets said lifter portion, said viewer directed toward the distal end portion of the lifter portion; and,

said, elongate arm having a longitudinal center, and said base portion meets said lifter portion substantially near said longitudinal center[in the middle of said elongate arm].

27. (Amended) The intubation instrument of claim 26, wherein said viewer is a Complementary Metal Oxide Semiconductor [CMOS] camera.

28. (Amended) The intubation instrument of claim 26[27], wherein said lifter portion is pivotally secured to said base portion.

29. (Amended) The intubation instrument of claim 28, further including a Light Emitting Diode [an LED light] operably secured to said lifter portion.

30. (Amended) The intubation instrument of claim 27[29], further including a display operably secured to said camera.

--31. The intubation instrument of claim 1, wherein said first defined length and said second defined length are substantially the same length.

32. The intubation instrument of claim 2, further including a light operably secured to said lifter portion.

33. The intubation instrument of claim 32, wherein said light is a Light Emitting Diode.

34. The intubation instrument of claim 1, wherein said lifter portion is pivotally secured to said base portion at a pivot point.

35. The intubation instrument of claim 34, further including a locking mechanism for actuating and holding said lifter portion in a predetermined position about said pivot point.

36. The intubation instrument of claim 2, further including a display for viewing video output from said viewer.

37. The intubation instrument of claim 36, wherein said display is remotely connected to said camera.

38. The intubation instrument of claim 19, further including a light operably secured to said lifter portion.

39. The intubation instrument of claim 23, wherein said light is a Light Emitting Diode.

40. The intubation instrument of claim 25, wherein the portion of the intubation instrument for insertion into a patient through the patient's mouth is elongate and has a longitudinal center, and said base portion meets said lifter portion substantially near said longitudinal center.

41. The intubation instrument of claim 25, wherein said viewer is a Complementary Metal Oxide Semiconductor camera.

42. The intubation instrument of claim 25, wherein said lifter portion is pivotally secured to said base portion.

43. The intubation instrument of claim 42, further including a Light Emitting Diode operably secured to said lifter portion.

44. The intubation instrument of claim 41, further including a display operably secured to said camera.--

ATTACHMENT C
Proposed Redlined changes to the drawings

Fig. 1

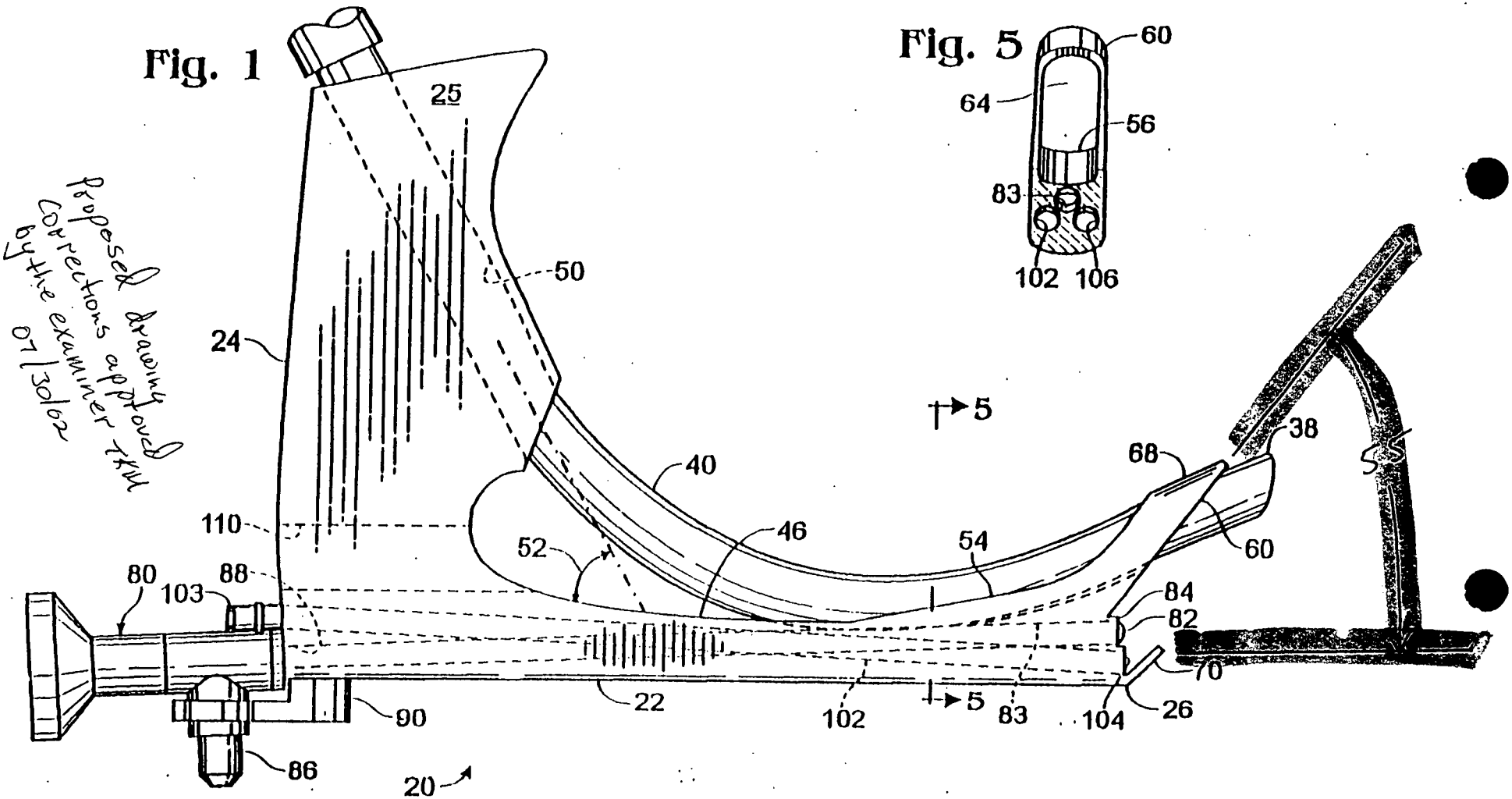


Fig. 5

Proposed drawing Corrections approved by the examiner TKH 07/30/02

Fig. 3

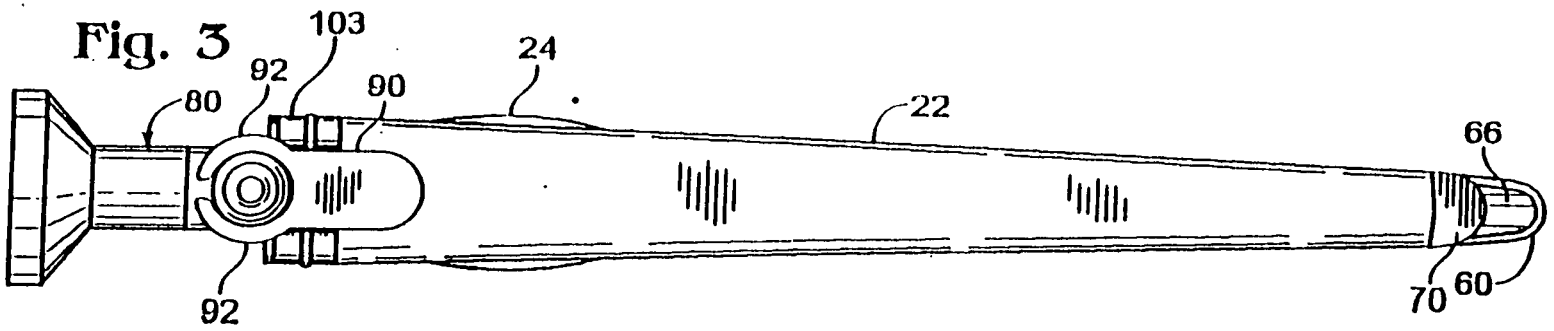


Fig. 2

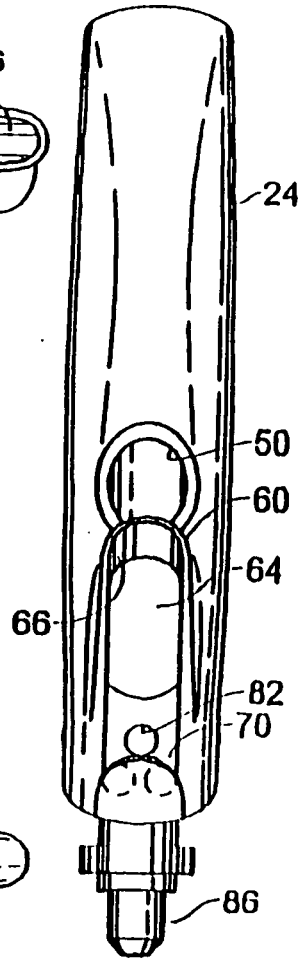
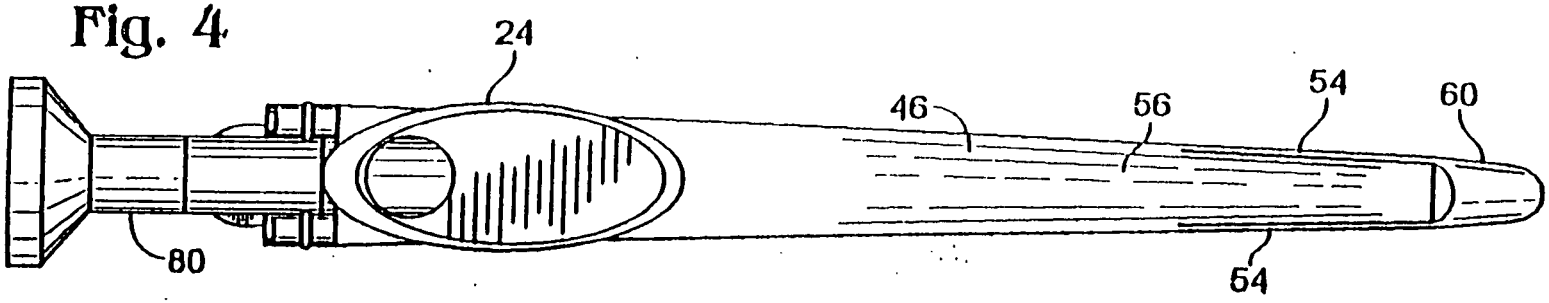


Fig. 4



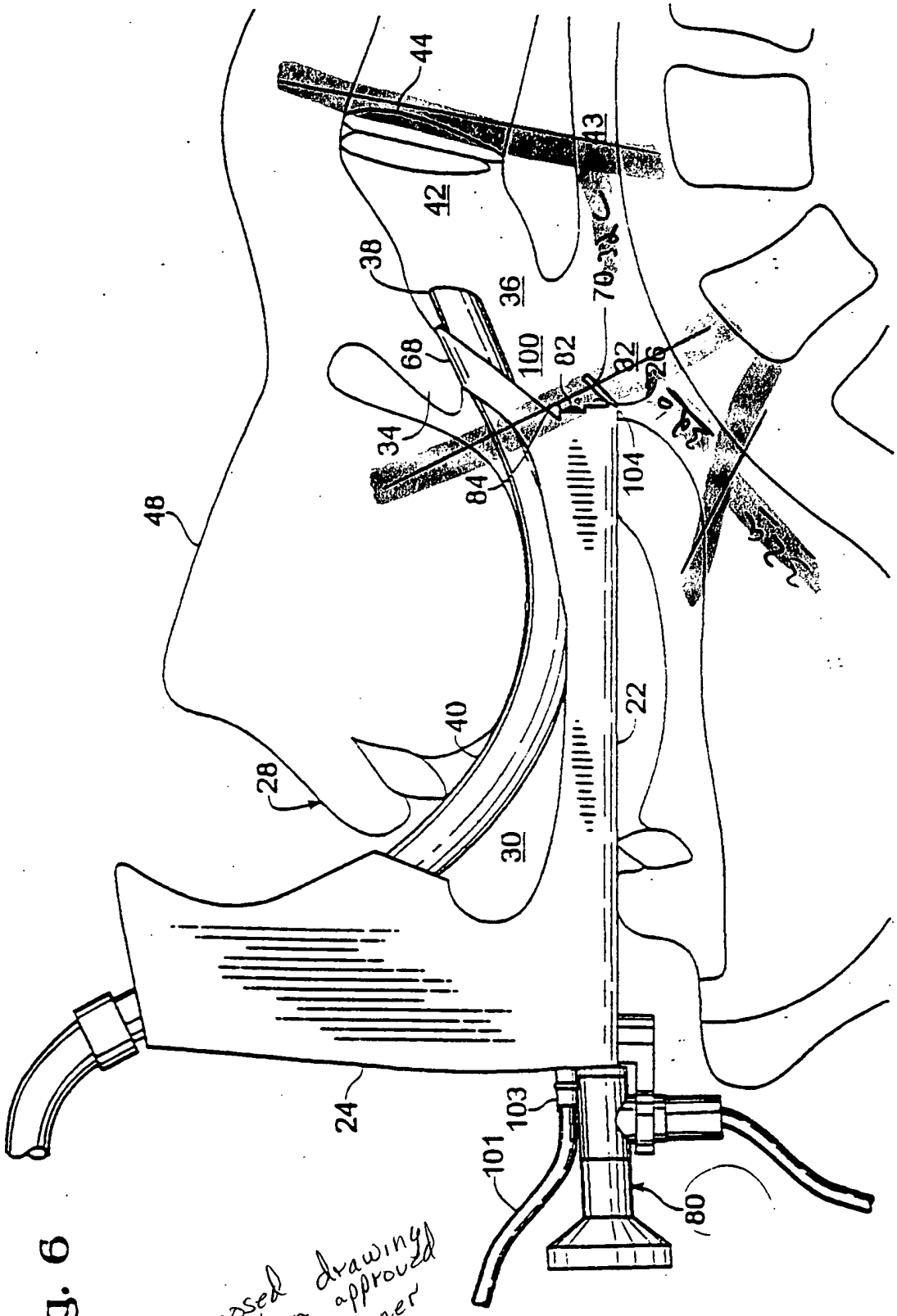


Fig. 6

Proposed drawing correction approved by the examiner
TKM
07/30/02

FIG. 7

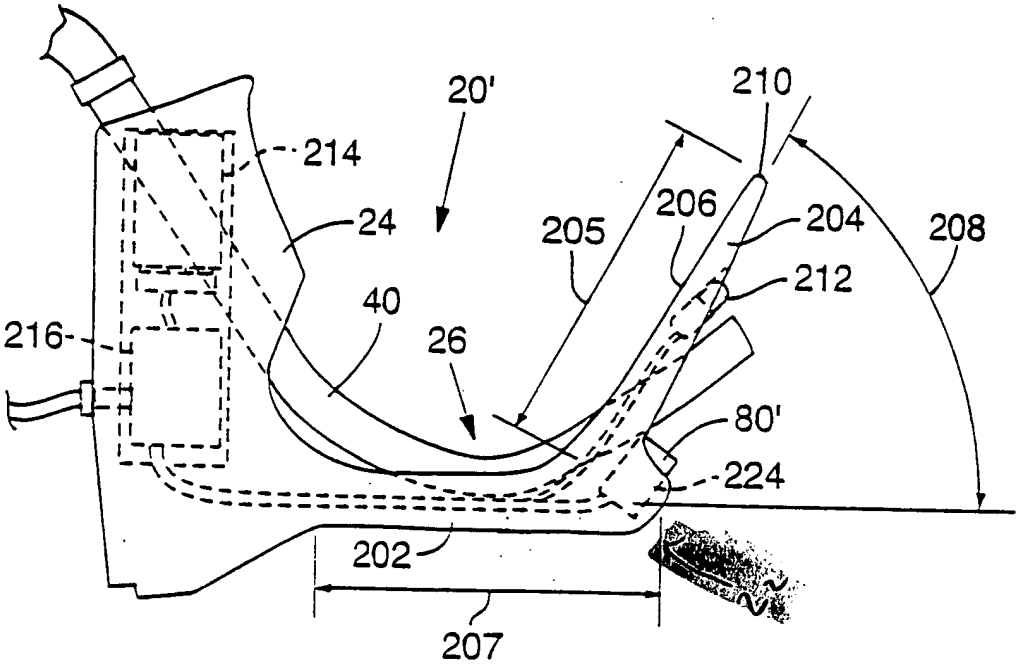
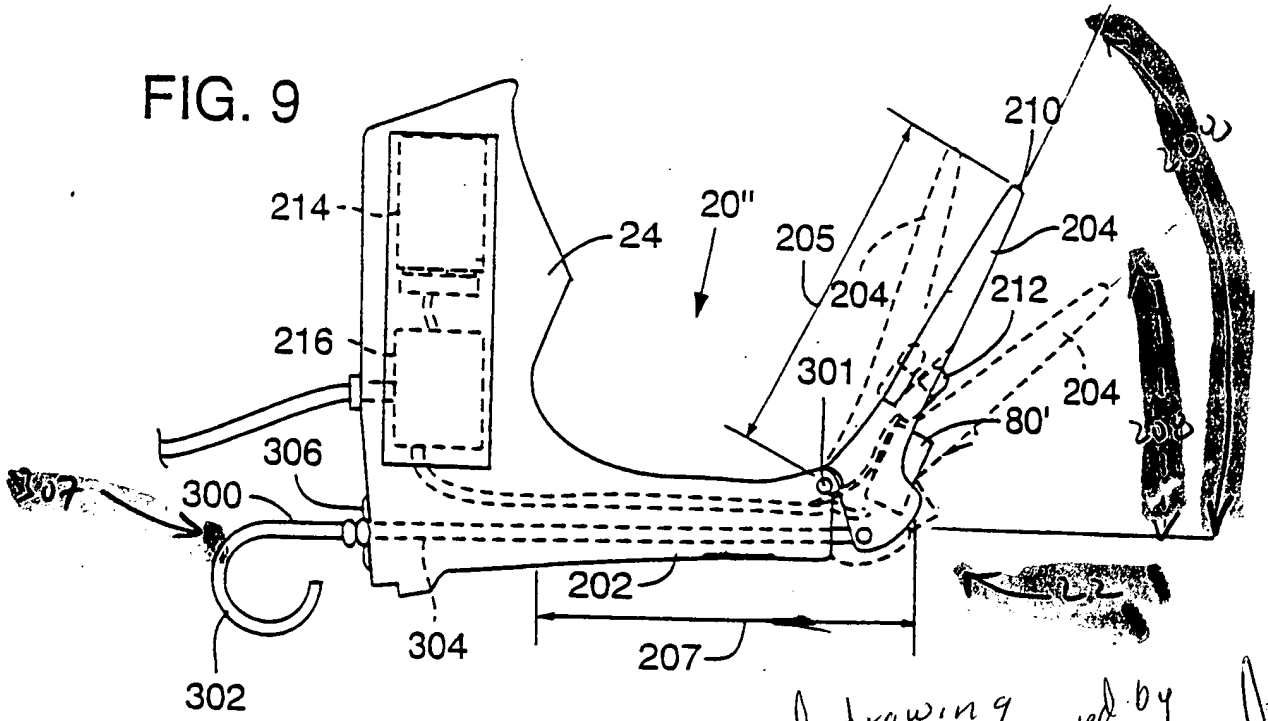
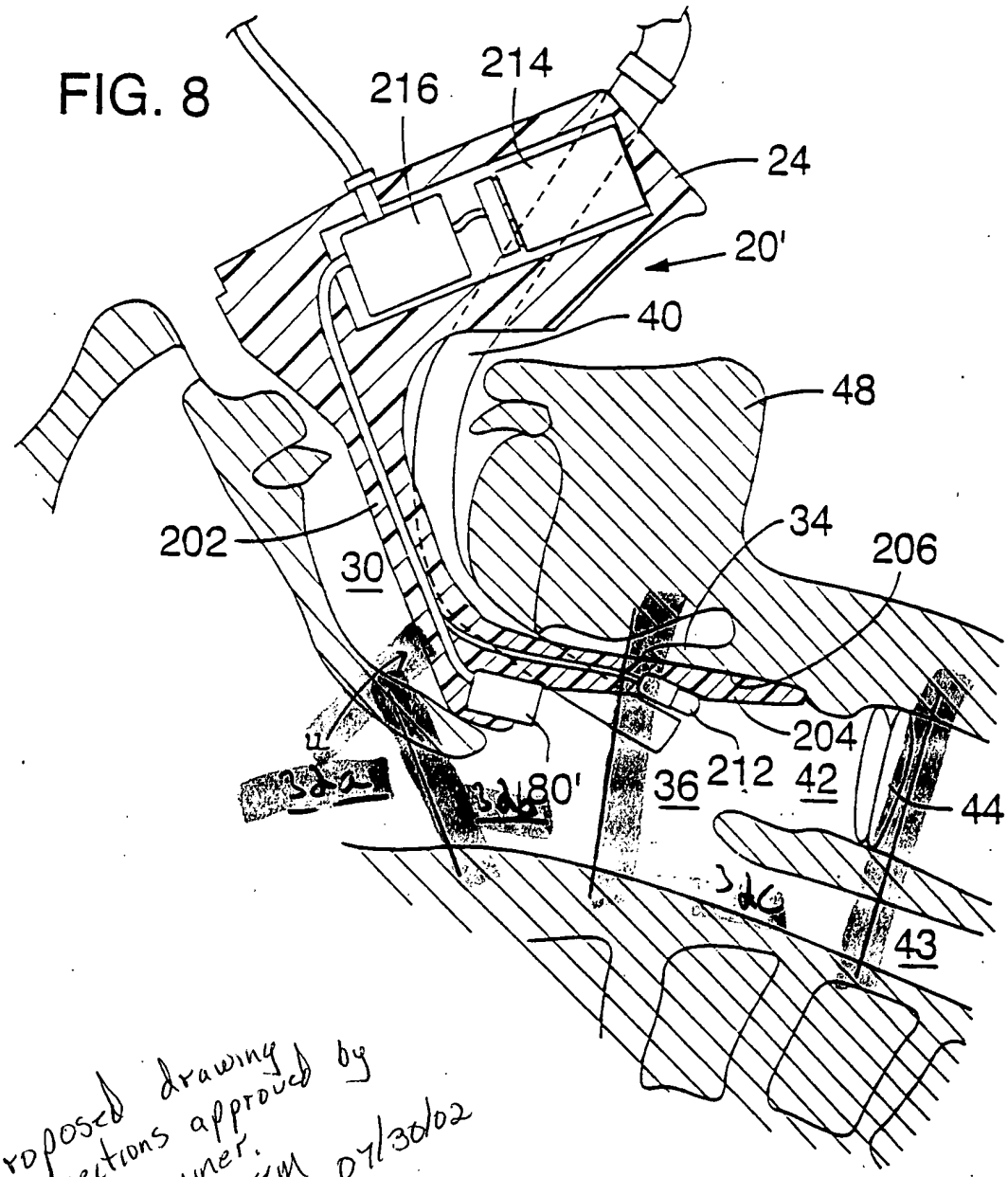


FIG. 9



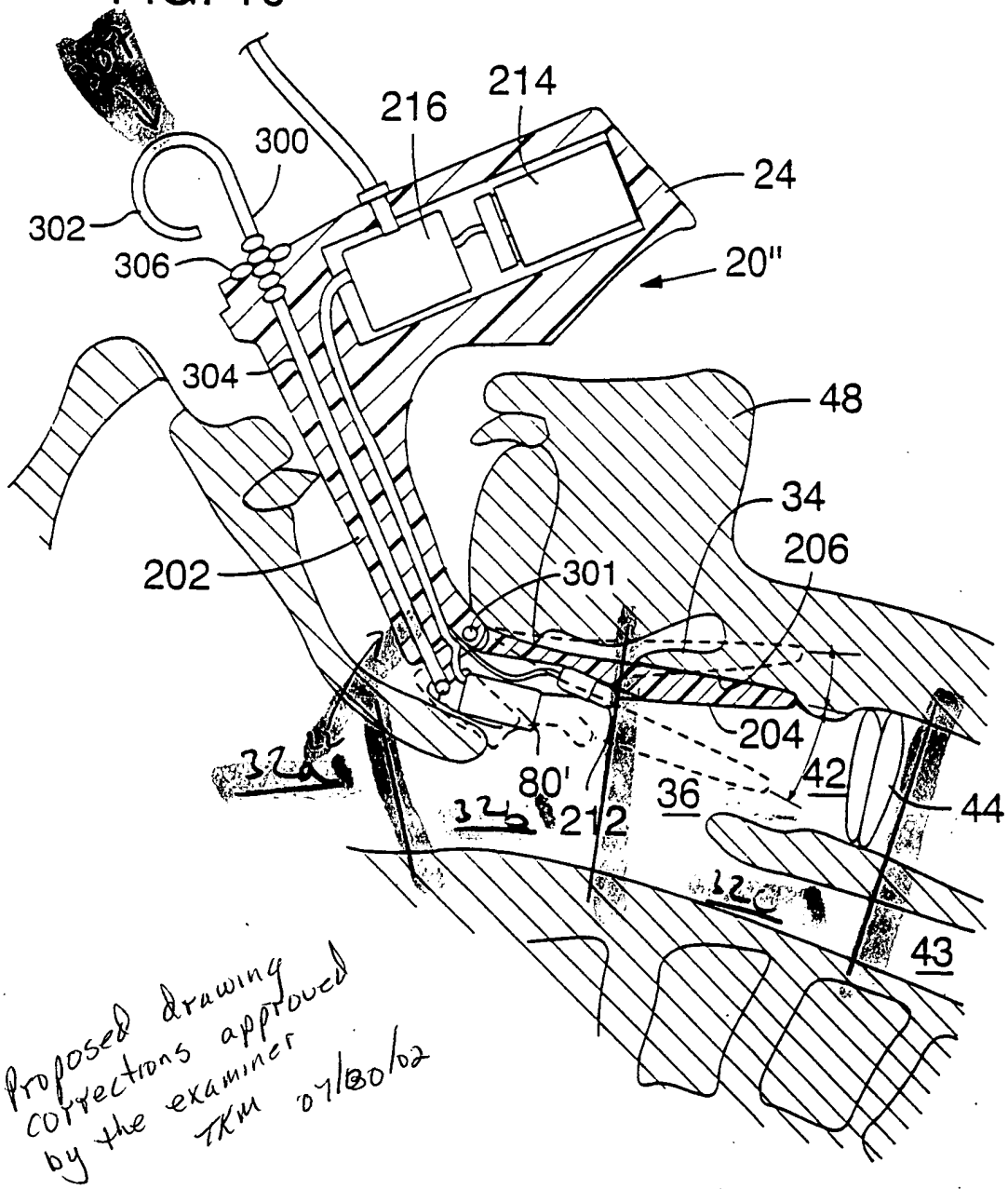
Proposed drawing corrections approved by the examiner TKM 07/30/02

FIG. 8



Proposed drawing corrections approved by the examiner. TXM 07/30/02

FIG. 10



Proposed drawing corrections approved by the examiner TKM 07/30/02

FIG. 11A

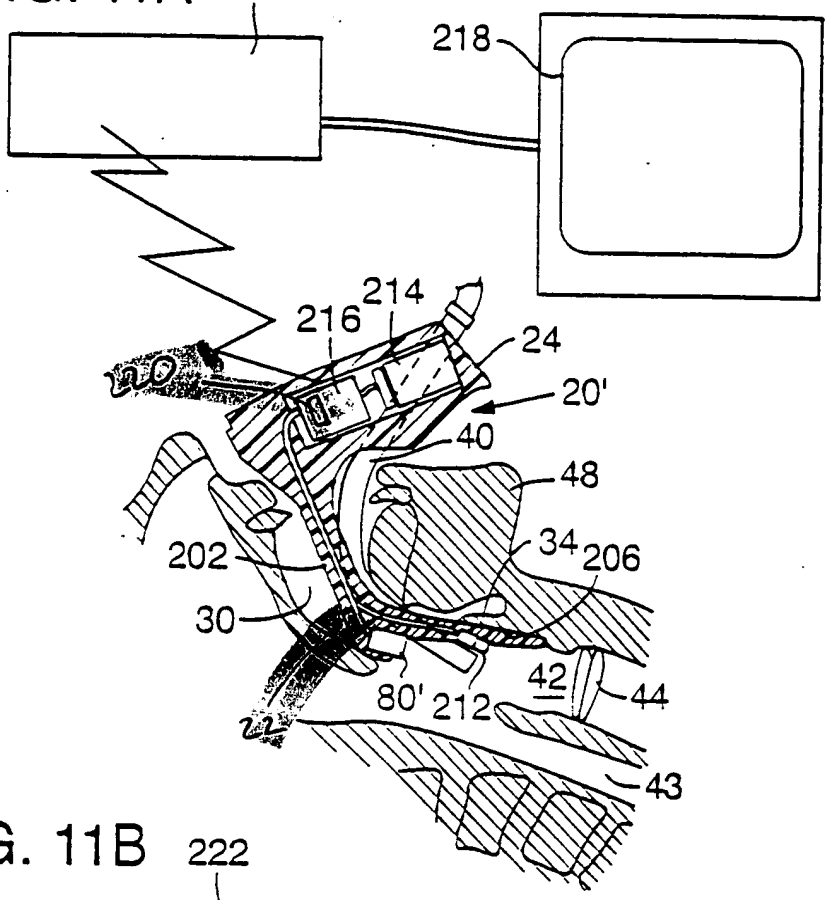
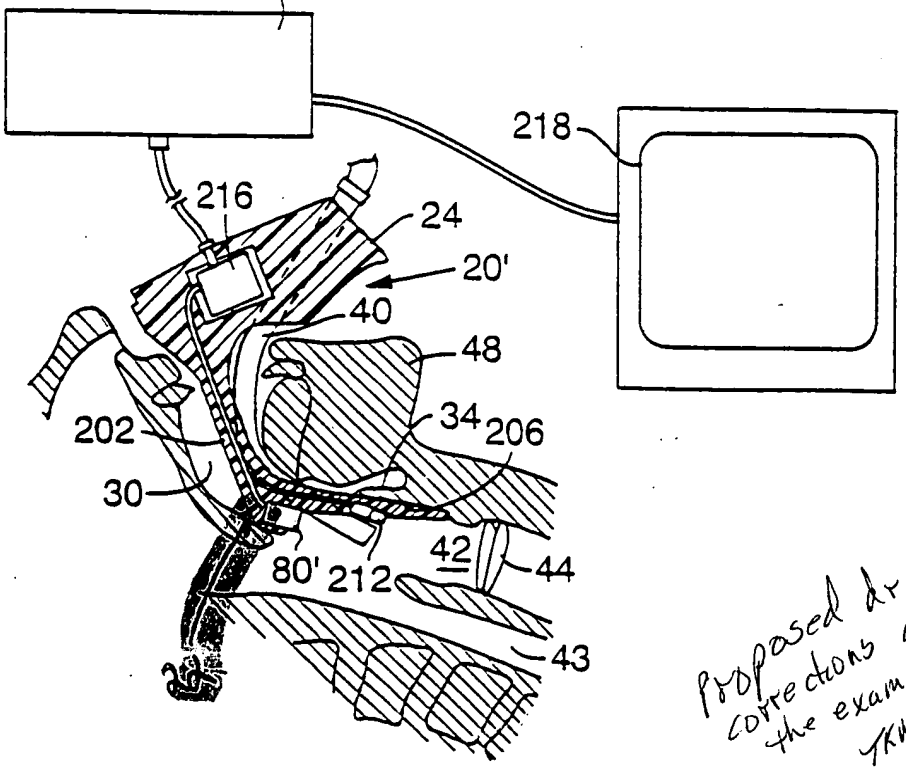


FIG. 11B



Proposed drawing corrections approved by the examiner. TKM 07/30/02